

DSJ1&2-PR Exh 544

From: Clark, Jessica
Sent: Tuesday, October 25, 2016 7:32 AM
To: Poshni, Faiza; Feniger, Angela; Jones, Heather
Cc: Clark, Jessica; Conti, Joan; Dec, John; Shukla, Jaydeep; Brantley, Eric; Roman, Sonia
Subject: RE: SOMs
Attachments: SOP-SO-0002.doc; SOP-SO-0004.doc

Good morning Faiza/Angela/Heather.

I am reviewing SOP's for our department and believe SOP SO-0002 (copy attached) should be retired since SOM is now handled by Eric Brantley in Huntsville.

The SOP does address our department's quarterly DEA audit process, but I would propose to modify SOP SO-004 (copy also attached) to include reference to the DEA audit.

SOP SO-002 also addresses monthly Compliance reporting.

Heather/Angela,

When the transfer of all controlled substances to Huntsville is complete in early November, will you need Joan to provide any controlled substance reporting on a forward basis?

Please review when you can and please provide feedback.

Thank you.

Jessica Clark
Director, Customer Operations
Par Pharmaceutical | Six Ram Ridge Road | Chestnut Ridge, NY 10977
Phone: 845-364-4819 | Fax: 201.391.5217
Jessica.Clark@parpharm.com



From: Shukla, Jaydeep
Sent: Monday, April 11, 2016 3:52 PM
To: Clark, Jessica
Cc: Feniger, Angela; Poshni, Faiza
Subject: RE: SOMs

Thank you Jessica!

Jaydeep Shukla | Specialist, DEA Compliance
Par Pharmaceutical | 2 Ram Ridge Road | Chestnut Ridge, NY 10977
Phone: 845.573.5585 | jaydeep.shukla@parpharm.com
www.parpharm.com



From: Clark, Jessica
Sent: Monday, April 11, 2016 3:51 PM
To: Shukla, Jaydeep
Cc: Feniger, Angela; Poshni, Faiza
Subject: RE: SOMs

Hi Jaydeep,

Yes, we evaluate controlled substance orders based on customer provided usage and/or customer typical purchase patterns.

Jessica Clark
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Jessica.Clark@parpharm.com



From: Shukla, Jaydeep
Sent: Thursday, April 07, 2016 11:42 AM
To: Clark, Jessica
Cc: Feniger, Angela; Poshni, Faiza
Subject: SOMs

Hi Jessica,

Is your group evaluating controlled substance orders as per SOP-SO-002 suspicious order monitoring?

Thank you,
Jaydeep

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PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

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|--|--|
| Title: SUSPICIOUS ORDER MONITORING (SOM) | |
| Department: SO | Document No: SOP-SO-0002 Version: 1.6 |
| Legacy Document ID: SO002.1 | Page: 1 of 4 |

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I. PURPOSE

Define process of Suspicious Order Monitoring (SOM) for all controlled substances ordered directly by Par Trade Customers via a Purchase Order.

II. POLICY

As determined by Sales Operations with guidance from Quality Compliance ensuring we are in line with DEA requirements.

III. ROLES AND RESPONSIBILITIES

Sales Operations/Account Services to monitor applicable Par Trade Customer Purchase Orders for any notable variations in ordering patterns.

IV. PROCEDURE

Par's Trade customers transmit Controlled Purchase Orders via EDI and minimal Purchase Orders come in via fax/scan-email.

Weekly replenishment Purchase Orders are analyzed by Account Service Executives verses Customer provided usages.

If quantities are higher than the average transmission it is questioned.

The Buyer is contacted to review, a written request is asked as to the reason for the increase.

It is reviewed to ensure it is correct and warranted.

Seasonal changes are monitored if applicable to the product.

Monthly reports are generated by Account Services and sent to Quality Compliance for submission to the DEA on a quarterly basis; only for CII and CIII Narcotic products.

Par's top Trade Customers were asked to sign a document stating usages.

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Customer Usage grids are created for each controlled drug distributed as a benchmark to monitor Customer Purchase Orders.

Customers may have a change in usage when reported or uncovered grid would then get updated to reflect accordingly.

Controlled Substance product launch

100% audit conducted for all customers purchasing product before it ships for the first time.

<https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp>

100% audit conducted on a quarterly basis post launch by use of above DEA site is completed for all Trade Customers DEA registrations that purchase controlled substances from Par. This is to ensure we are not shipping to Trade Customers who may have a suspended license and not have communicated to PAR in a timely manner.

Reporting Suspicious Criminal Activities

If criminal activity is suspected, report the following to the state agencies that licensed the facility (e.g. board of pharmacy) and Food and Drug Administration (FDA), as well as Drug Enforcement Administration (DEA) for controlled substances within three days of suspecting criminal activity.

V. EXTERNAL REFERENCES

Sample of a Customer Usage Letter at Product Launch

VI. REVISION HISTORY

| Revision | Description of Changes |
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| Title: <u>PRESCRIPTION DRUG ORDER MONITORING</u> | |
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I. PURPOSE

Define process of Prescription Drug Order Monitoring for RX drugs ordered directly by Par Trade Customers via a Purchase Order.

II. POLICY

- A. As determined by Sales Operations with guidance from Quality Compliance ensuring we are in line with compliance guidelines.
- B. If the Prescription Drug Order Monitoring process does not meet the requirements of this SOP and criminal activity or suspicious product is suspected (refer to SOP QA109: Notification process to the Federal and State Agencies (DEA, New York State Board of Pharmacy)).

III. ROLES AND RESPONSIBILITIES

Sales Operations/Account Services to monitor applicable Par Trade Customer Purchase Orders for any notable variations in ordering patterns.

IV. PROCEDURE

Par's Trade customers transmit Prescription Drug Purchase Orders via EDI and minimal Purchase Orders come in via fax/scan-email.

Weekly replenishment Purchase Orders are analyzed by Account Service Executives verses Customer provided usages.

If quantities are higher than the average transmission it is questioned.

The Buyer is contacted to review, a written request is asked as to the reason for the increase.

It is reviewed to ensure it is correct and warranted.

Seasonal changes are monitored if applicable to the product.

Customers may have a change in usage when reported tracking docs would then

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get updated to reflect accordingly.

100% audit conducted on a quarterly basis for Trade Customers State License. This is to ensure we are not shipping to Trade Customers who may have a suspended license and not have communicated to PAR in a timely manner.

V. EXTERNAL REFERENCES

QA109 :Notification process to the Federal and State Agencies (DEA, New York State Board of Pharmacy)

VI. REVISION HISTORY

| Revision | Description of Changes |
|----------|----------------------------|
| | <u>No changes required</u> |

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